

Office Action Summary	Application No. 09/892,993	Applicant(s) BROWN ET AL.	
	Examiner BLESSING M. FUBARA	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges receipt of request for continued examination filed under 37 CFR 1.114, amendment and remarks filed 11/02/07. New claims 39-44 are added. Claims 26-28 are amended. Claims 26-44 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/02/07 has been entered.

Previous rejections and objections that are not reiterated herein are withdrawn.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 26-28 and 33-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Niederauer et al. ("Evaluation of multiphase implants for repair of focal osteochondral defects in goats," in *Biomaterials*, Vol. 21, Issue 24, pp 2561-2574, 15 Dec. 2000, cited in applicant's specification at paragraph [0008] of the published application).

Niederauer describes the use of biodegradable multiphase scaffold for repair of articular cartilage (abstract); the multiphase scaffold comprises polymer and ceramic phases (Table 1 and 3rd and 4th full paragraphs, left column of page 2563) meeting the claimed scaffold having a ceramic and polymer phase; the phases are glued together using a solvent (page 2563, first three lines of text in right column) representing the discrete phases of scaffold of the claims and also meets claim 33 and also of claims 34-44 with the pores within the phases meeting the plurality of pores claimed in claims 39-41; since the ceramic and polymer phases are placed next to each other, the phases would inherently communicate or interact at the interphase/junction region of the ceramic and polymer phases so that claims 42-44 are met; boring a receptacle space at the gradient junction of the site of injury as recited in claim 26-28 read on the experimental design of Niederauer where defect sites are made in the right and left stifles and bilateral arthrotomies performed to place the implants (paragraph 2.4 at page 2564); the scaffold is implanted into the prepared knees. Niederauer is silent on placing the ceramic phase next to the bony tissue and placing the polymer phase next to the cartilage tissue. However, it is known in the art that ceramics closely resemble constituents of natural bone. Therefore, it would have been obvious

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to one of ordinary skill in the art at the time the invention was made to use the teachings of Niederauer to repair articular cartilage by placing the ceramic phase of the scaffold next to the bony tissue since the ceramic material closely resembles the bony tissue so that the bony tissue would grow into the ceramic tissue during the repair process.

5. Claims 26-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Niederauer et al. ("Evaluation of multiphase implants for repair of focal osteochondral defects in goats," in *Biomaterials*, Vol. 21, Issue 24, pp 2561-2574, 15 Dec. 2000, cited in applicant's specification at paragraph [0008] of the published application) in view of Vyakarnam et al. (US 6,306,424).

Niederauer is discussed above for rendering prima facie obvious claims 26-28 and 33-44. While Niederauer describes a scaffold that is made up of porous polymer phase and porous ceramic phase, Niederauer does not describe any of the porous phases as foamed material as claimed in claims 29-32. However it is known to use porous and foamed scaffold for repair or regeneration of tissues as taught in Vyakarnam (column 1, lines 17-21 and Title) and the porous structures are formed by lyophilization (column 4, lines 11-24). The foamed scaffold meets the limitation of claim 29; lyophilization to make foamed structure meets claims 30-32. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to form porous foamed scaffold structure by lyophilization with the expectation of obtaining organization at the microstructural level that facilitates tissue repair/regeneration.

Response to Arguments

6. Applicant's arguments filed 11/02/07 have been fully considered but they are not persuasive.

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7. Applicant argues Niederauer fails to disclose or suggest the method of claim 26 based on the arguments that a) the scaffold recited clearly has two phases; b) the ceramic and polymer phases of Niederauer are blended together and the phases glued together and that there is no disclosure in Niederauer of an interphase region; c) the scaffold of the invention has discrete ceramic layer and discrete polymer layer and an interphase region that is situated between the ceramic and polymer layers; d) the ceramic layer is placed adjacent to the bony tissue and the polymer layer is placed next to the cartilaginous tissue and although the examiner concedes that Niederauer does not teach the aspect of placing the scaffold next to the bony and cartilaginous tissues, it would not also be obvious to the skilled artisan to modify the blended phases of Niederauer to form discrete phases; e) the Vyakarnam reference does not disclose or suggest any interaction between a polymer phase and a ceramic phase and an interphase region where the polymer and ceramic phases are interacting through the pores so that applicant argues that the Vyakarnam reference alone or in combination with Niederauer does not anticipate or render obvious the claim 26 and claim 26 is in condition for allowance. Therefore, applicant says that claims 27-44 that depend directly or indirectly on claim 26 are thus allowable.

8. Response:

9. Niederauer renders obvious claims 26-28 and 33-44 as described in the rejections and Niederauer in view of Vyakarnam renders obvious claims 29-32 as described in the rejections above. Regarding a), it is noted that the Niederauer describes a scaffold that comprises ceramic and polymer phases that meet the discrete phases of the claimed scaffolds and applicant's admission of the gluing together of the polymer and ceramic phases further represents discrete phases with the region at which the two phases are glued together representing the interphase region such that argument b) is not persuasive; regarding c) it is noted that the scaffold of

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Niederauer, having the polymer phase and the ceramic phase glued together has a region between the ceramic and the polymer phases that represents and interphase the presence of the interphase region between the ceramic and polymer phases in Niederauer thus meets the structure of the claimed scaffold having an interphase region and discrete polymer and ceramic phases such that the polymer and the ceramic phases being porous interact through the interphase region; regarding d) it is noted that the skilled artisan does not have to modify blended phases because Niederauer teaches gluing the ceramic and polymer phases as acknowledged by applicant in the remarks on page 11 at line 5 and because the ceramic closely resembles the constituents of natural bone, the skilled artisan would naturally place the ceramic phase next to the bony tissue to achieve the expected result of articular cartilage repair during which the bony tissue would grow into the ceramic phase. Once the ceramic phase is placed next to the bony tissue, it would only follow that the polymer phase would be placed next to the cartilaginous tissue. Regarding e), it is noted that Vyakarnam was not relied upon for teaching discrete polymer and ceramic phases, but was relied upon for teaching porous and foamed scaffold for repair and regeneration of tissues with the foamed scaffold meeting the limitations of claims 30-32. Therefore, the combination of Niederauer and Vyakarnam renders obvious the claimed invention in which foamed and porous scaffold is used. By the same argument and the rejections above, the claims dependent on claim 26 are rendered obvious by Niederauer, and Niederauer in combination with Vyakarnam.

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Blessing M. Fubara/
Examiner, Art Unit 1618